

Application No. 10/505,239

Reply to Office Action

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Restriction Requirement

The Office Action has set forth a restriction requirement. The grouping of claims subject to restriction are set forth in the Office Action as follows:

Inventions 1-15 (claims 1-28, 49-64, 67, and 88-111) directed to a conjugate comprising ligands with one of SEQ ID NOs: 5-18 and 20;

Inventions 16-30 (claims 68, 69, and 78-81) directed to a method of treating cancer in a mammal comprising administering a conjugate comprising linker FALA and one of SEQ ID NOs: 5-18 and 20;

Inventions 31-45 (claims 70 and 71) directed to a method of delivering a cytotoxic agent by administering a conjugate comprising the linker VLALA and one of SEQ ID NOs: 5-18 and 20;

Inventions 46-60 (claims 76 and 77) directed to a method of delivering a cytotoxic agent by administering a conjugate comprising the linker ChaLALA, ChaChaLAL, NalChaLaL, or NalLALA and one of SEQ ID NOs: 5-18 and 20;

Inventions 61-75 (claims 112, 113, and 116-119) directed to a method of delivering a cytotoxic agent by administering a conjugate comprising the linker ALAL and one of SEQ ID NOs: 5-18 and 20; and

Inventions 76-90 (claims 114 and 115) directed to a method of delivering a cytotoxic agent by administering a conjugate comprising the linker ALALA and one of SEQ ID NOs: 5-18 and 20.

Species Election Requirement

The Office Action also requires that Applicants elect one species from each of the following groups (see page 3, item 4, of the Office Action):

- (a) linkers with SEQ ID NOs: 1-4 and 21-24;

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- (b) cytotoxic agents in claims 14, 28, 62, 98, and 109;
- (c) receptors in claims 4, 18, 52, 88, and 99; and
- (d) species within the sequences of ligands represented by SEQ ID NOs: 9, 13, 15, and 16 (if such ligands are elected).

Applicants note that if the Office Action requires an election of a particular sequence from among SEQ ID NOs: 5-18 and 20, then the requirement that Applicants elect a receptor in Group (c) is redundant (and broader in scope) than the particular sequence elected.

Applicants' Election with Traverse

In response to the restriction requirement, Applicants elect, with traverse, claims 1-28, 49-64, 67, and 88-111 (entitled "Inventions 1-15" by the Office). Since the Office Action requires that Applicants elect a single sequence from SEQ ID NOs: 5-18 and 20, Applicants elect, with traverse, SEQ ID NO: 20 (claims 1-4, 6, 14-18, 20, 28, 49-52, 54, 62-64, 67, 86-88, 90, 98, 99, 101, 110, and 111).

Regarding the election of species, Applicants elect, with traverse, the following:

- (a) an embodiment wherein the linker is FALA (SEQ ID NO: 1) (claims 1-14, 63, 68, 69, 78, and 79);
- (b) an embodiment wherein the cytotoxic agent is a derivative of cemadotin (claims 1-119); and
- (c) an embodiment wherein the receptor is the gastrin (cholecystokinin B) receptor (claims 1-6, 14-20, 28, 49-52-54, 62-64, 67-71, 76-81, 86-90, 98-101, and 110-119).

While Applicants have provided an election for the aforementioned species, the species election merely is intended to aid the Examiner in the search and examination of the present patent application. The election is by no means indicative of Applicants' willingness to ultimately limit the claims of the present patent application to these species. Consistent with an election of species requirement, and as acknowledged in the Office Action,

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Applicants will be entitled to consideration of other species falling within the generic claims if the elected species are found to allowable.

Discussion of Restriction and Species Election Requirements

The subject application is a U.S. national stage application based on international application PCT/US03/06344. The Office Action alleges that the inventions defined by the claims of Groups 1-90, and the alleged species encompassed thereby, do not relate to a single general inventive concept under PCT Rule 13.2 because they lack the same "special technical features."

Under PCT Rule 13.2, a group of inventions is considered linked to form a single general inventive concept where there is a technical relationship among the inventions that involves at least one common or corresponding special technical feature. PCT Rule 13.2 defines the term "special technical features" as meaning those technical features that define the contribution which each claimed invention, considered as a whole, makes over the prior art (see M.P.E.P. § 1893.03(d)).

All of the claims are linked by the technical feature of a conjugate comprising a ligand and a cytotoxic agent linked by a linking molecule. In at least this respect, the claims all share a special technical feature.

Further, certain subgroups of the claims have other special technical features in common. For example, claims 1-14, 63, 68, 69, 78, and 79 all share the special technical feature of a ligand bound to a cytotoxic agent by a linking molecule of FALA (SEQ ID NO: 1). Claims 1-3, 63, 68, 69, 78, and 79 are generic to the ligand and cytotoxic agent, wherein claims 4-14 recite specific ligands and cytotoxic agents that can be used. The recitation of the specific ligands and cytotoxic agents does not change the nature of the claims as sharing the above special technical feature.

The Office Action alleges that the sequences represented by the SEQ ID NOs. disclosed in the independent claims are drawn to ligands that bind to a plethora of receptors with no disclosed common property (see page 3, lines 1-3, of the Office Action). As discussed above, the independent claims (e.g., claim 1) recite a particular linker sequence

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(e.g., SEQ ID NO: 1), but the claims are generic to the SEQ ID NOs of the ligands, as well as the particular cytotoxic agents.

To the extent the Office Action requires restricting the invention to specific embodiments of the dependent claims, such practice is contrary to the PCT rules. PCT Rule 13.4 states that "Subject to Rule 13.1, it shall be permitted to include in the same international application a reasonable number of dependent claims, claiming specific forms of the invention claimed in an independent claim, even where the features of any dependent claim could be considered as constituting in themselves an invention." The Administrative Instructions under the PCT, at Annex B, also states:

Unity of Invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims. ... If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims. In particular, it does not matter if a dependent claim itself contains a further invention.

(Administrative Instructions Under the PCT, Annex B, Part I). Thus, the genus claims (e.g., claims 1-3, 63, 68, 69, 78, and 79) cannot properly be restricted to the subject matter of the species (e.g., dependent claims 4-14).

Accordingly, Applicants respectfully submit that the restriction and election of species requirements are improper and request that they be withdrawn.

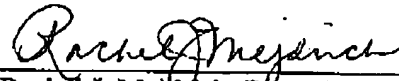
Conclusion

Applicants respectfully submit that the patent application is in condition for allowance. If, in the opinion of the Examiner, a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to call the undersigned agent.

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Respectfully submitted,



Rachel J. Mejdich, Reg. No. 53,477
LEYDIG, VOIT & MAYER, LTD.
Two Prudential Plaza, Suite 4900
180 North Stetson Avenue
Chicago, Illinois 60601-6731
(312) 616-5600 (telephone)
(312) 616-5700 (facsimile)

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